| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| | 150166 | A. BUILDING 00<br>B. WING | 01/10/2013 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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| PINNACLE HOSPITAL | 9301 CONNECTICUT DR<br>CROWN POINT, IN 46307 |

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| A0000 | This visit was for one Federal hospital complaint<br>investigation of an unaccredited facility.<br><br>Complaint Number:<br>IN00118590<br>Substantiated: Deficiencies cited.<br><br>Date: 1/10/13<br><br>Facility Number: 006619<br><br>Surveyor: Jacqueline Brown, R.N.<br>Public Health Nurse Surveyor<br><br>QA: claughlin 02/11/13 | A0000 | | |

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Any defiencystatement ending with an asterisk (*) denotes a deficency which the institution may be excused from correcting providing it is determined that other safegaurds provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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| A0309 | 482.21(e)<br>EXECUTIVE RESPONSIBILITIES<br>The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:<br>Based on policy and procedure review and staff interview, the facility failed to ensure that the Quality/Risk Director was notified of potential risk to patient safety allegations at the time the allegations were made in order to conduct timely follow up and investigation.<br><br>Findings:<br><br>1. Policy No.: QA titled, "Quality Mgmt Department Scope of Care", revised/reapproved 5/2012, was reviewed on 1/10/13 at approximately 10:40 AM and indicated on pg:<br>A. 1, under Organizational Plan and Structure section, points 3.1 and 3.2, "Quality/Risk Management Services functions under the direction of the Director of Quality/Risk Management. The Director, Quality/Risk Management, is responsible for the daily operations of the department and has the authority and responsibility for all aspects of planning, implementing, monitoring and evaluating the services and care delivered by the department." | A0309 | The hospital hired a new Quality Risk Manager that has been fully oriented regarding her responsibilities under the applicable policies. The Manager has been fully integrated into operation of the Hospital and is engaged in her role. To ensure that all personal understand the role of the Quality Risk Manager the Hospital will hold a general staff meeting for all personal on or before March 12, 2013 regarding this issue. By way of further response, the Hospital notes following:Finding 2A: The allegation regarding the surgical tech witnessing an anesthesiologist putting Propofol in his pocket was reported to the COO of the Hospital ( who was temporarily serving as the Quality Risk Manager while the new Manager was trained ) who reported it to the Medical Director, the Chairman of the Medical Advisor Committee and Hospital counsel. The surgical tech was interviewed by the COO and Hospital counsel who denied making the accusation and refused to cooperate. In addition, the anesthesiologist denied to the CEO that he | 03/13/2013 |

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| | B. 3, under Scope of Care/Activities includes, but not limited to section: Patient Safety, prevention of medical variances that can actually/potentially result in patient injury/harm through an environment that encourages: recognition and acknowledgement of risks to patient safety and medical/health care errors; initiation of actions to reduce these risks; internal reporting of what has been found and the actions taken."<br>C. 3 & 4, under Quality/Performance Improvement: an overall assessment of the efficiency and/or effectiveness of performance activities and/or care...Identifying problems/reasons for improvement to achieve external and internal customer satisfaction, improving organization performance or achieving strategic goals, analyzing root cause of identified problems/opportunities for improvement and implementing countermeasures to reduce or eliminate identified root causes and improve care...reporting and follow-up of unusual occurrences involving patients and families, reduction, minimization and/or prevention of exposure to risk and/or litigations."<br><br>2. Personnel P6 was interviewed on 1/10/13 at approximately 10:06 AM and confirmed:<br>A. an allegation was made by a surgical | | pocketed the propofol. During the survey, the anesthesiologist was questioned by the surveyor and conceded that he did in fact pocket the propofol. The Quality Risk Manager was notified of the admission and she has referred the matter to the Peer Review Committee which will consider what action should be taken at its meeting on March 13, 2013. The Quality Risk Manager, and Manager of Surgical Services will hold a meeting with the anesthesia department staff on or before March 12, 2013 to discuss the Policies relating to the proper handling of drugs and the need to report and cooperate with the Hospital Administration when it investigates these type of incidents In addition, the anesthesiologists will be inserviced on the proper documentation for intraoperative medication useage of rate and dose. In addition, the Pharmacist had begun reviewing charts on surgical patients for proper use and documentation of anesthesia ( Propofol ) on a daily basis to confirm that the applicable policies are being followed. The Pharmacist will cease daily review when she determines that the policies are being followed and she will do a Quarterly Review of 30 charts to determine they they properly reflect use and documentation of anesthesia ( Propofol ). The Hospital has formed an | |

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| | tech that they witnessed an anesthesiologist putting Propofol in their pocket prior to a surgical procedure.<br>B. another allegation was made by a nurse that this same anesthesiologist left the facility while patients were still in the recovery room and threatened to have this nurse terminated if they reported it. This allegation was received via email from this nurse on 1/8/13.<br>C. the Quality/Risk Director was not made aware of either of these allegations and although they were recently hired and in training/orientation, he/she should have been made aware of these allegations as required by facility policy and procedure.<br><br>3. Personnel P3 was interviewed on 1/10/13 at approximately 9:32 AM and confirmed, he/shewere not made aware of these two allegations. | | Anesthesia Committee which will review along with the Qualtiy Council the results of the audits done by the Pharmacist on a Quarterly basis. Finding 2B: The Post Anesthesia nurse reported to the surgical manager during a department meeting that a physician left the facility while patients were still in recovery room and threatened to have this nurse terminated if they reported it. This incident occured on December 29, 2012, and was reported to the surgical manager on January 8, 2013. The manager notified the COO by email and the COO instructed the manager to request an incident report from the nurse, which was provided on January 13, 2013. The Quality Manager received the report on January 11, 2013 at 12:30. The matter was discussed with the Medical Staff President who referred it to the Peer Review Committee to consider at its March 13, 2013 meeting. In addition, the Quality Risk Manager will hold a meeting with thre anesthesia department regarding the applicable policies relating to the presence of an anesthesiologist in the surgical area and the requirement that the Hospital staff report deviations from those policies as soon as possible. | |

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| A0500 | 482.25(b)<br>DELIVERY OF DRUGS<br>In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.<br>Based on policy and procedure review, medical record review, and staff interview, the facility failed to implement written policies and procedures for the appropriate control, use, and monitoring of drugs according to policy and procedure for 3 of 5 (N2, N4, and N5) closed patient medical records reviewed.<br><br>Findings:<br><br>1. Policy No.: PHAR470 titled, "Medication Storage", revised/reapproved 5/2012, was reviewed on 1/10/13 at approximately 10:40 AM, and indicated on pg. 1, under Policy section, "It is the policy of [facility] that medications will be stored in a safe manner and to meet all applicable laws and regulations with regards to drug storage and security."<br><br>2. Policy No.: A-11 titled, "Anesthesia Care Protocol", revised/reapproved 5/2012, was reviewed on 1/10/13 at approximately 10:40 AM, and indicated on pgs. 6 & 7, under Practice Parameters and Procedures section, point I.7., "The anesthesiologist shall keep a complete | A0500 | Effective 2/15/13 the Hospital implemented a new Drug Utilization Review policy to monitor and enforce compliance with Hospital policies for control, use and monitoring of drugs. The policy requires a quality monitor to monitor appropriate control, use, and monitoring of drugs. The medical records will be reviewed in accordance with the Drug Utlization Review Policy. The medical records regarding Propofol will be reviewed daily to determine compliance for until such time as the records properly document the required information ( including dosage and rate ). 30 records or more will be reviewed quarterly for compliacne and reported to the Anethesia Committee. The Hospital is holding a mandatory meeting no later than March 12 with anesthesiologists to review the Hospitals Policies regarding drug control, use and monitoring including the following.1. Policy No: PHAR470 titled: " Medication Storage."2. Policy No: A-11 titled: "Anesthesia Care Protocol."3. New Drug Utilization Review Policy. The Hospital is forming an Anesthesia Committee of the medical staff on or before March | 03/13/2013 |

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| | record for each operation where he is in attendance on the approved anesthesia form. The Anesthesiologist is responsible for the recording of all events taking place during the induction, maintenance of, and emergence from anesthesia, including dosage and duration of all anesthetic agents, other drugs, and intravenous fluids."<br><br>3. Review of closed patient medical records on 1/10/13 at approximately 11:00 AM, indicated patient:<br><br>A. N2:<br>a. had a surgical procedure performed on 10/18/12, under general anesthesia starting at 06:54 AM.<br>b. per Omnicell Automated Medication Dispensing Report dated 10/18/12, the following was removed by D1 for N2 at:<br>i. 6:58 AM, one 100 ml vial of propofol 10 mg/1 ml.<br>ii. 8:12 AM, one 50 ml vial of propofol 10 mg/1 ml.<br>c. per Anesthesia Record dated 10/18/12:<br>i. D1 was listed as the anesthesiologist.<br>ii. at approximately 07:00 AM, 140 mg of propofol was administered.<br>iii. lacked documentation of rate and total dosage amount of propofol | | 13, 2013, that will meet quarterly to review Drug Utilization Review and related matters. In regards to the specific issue of Propofol, rate and total dose documented, will be reviewed daily by the Pharmacist to ascertain compliance is achieved. Pharmacist will determine if any deficiences are noted in the process. This information will be reported to the Anesthesia Committee and to Quality Council Committee. | |

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| | administered during the surgical procedure<br><br>B. N3:<br>a. had a surgical procedure performed on 10/17/12, under monitored anesthesia care (with sedation) starting at 11:09 AM.<br>b. per Omnicell Automated Medication Dispensing Report dated 10/17/12, the following was removed by D1 for N3 at 11:12 AM, one 50 ml vial of propofol 10 mg/1 ml.<br>c. per Anesthesia Record dated 10/17/12:<br>i. D1 was listed as the anesthesiologist.<br>ii. no propofol was administered during the surgical procedure.<br><br>C. N4:<br>a. had a surgical procedure performed on 10/17/12, under monitored anesthesia care (with sedation) starting at 11:29 AM.<br>b. per Omnicell Automated Medication Dispensing Report dated 10/17/12, the following was removed by D1 for N4 at 11:47 AM, one 20 ml vial of propofol 10 mg/1 ml.<br>c. per Anesthesia Record dated 10/17/12:<br>i. D1 was listed as the anesthesiologist.<br>ii. at approximately 11:30 AM, 60 mg of propofol was administered. | | | |

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| | iii. lacked documentation of rate and total dosage amount of propofol administered during the surgical procedure<br><br>D. N5:<br>a. had a surgical procedure performed on 10/17/12, under monitored anesthesia care (with sedation) starting at 11:54 AM.<br>b. per Omnicell Automated Medication Dispensing Report dated 10/17/12, the following was removed by D1 for N5 at 11:47 AM, one 50 ml vial of propofol 10 mg/1 ml.<br>c. per Anesthesia Record dated 10/17/12:<br>i. D1 was listed as the anesthesiologist.<br>ii. at approximately 12:00 PM, 60 mg of propofol was administered.<br>iii. lacked documentation of rate and total dosage amount of propofol administered during the surgical procedure<br><br>4. Patients N4 and N5 had propofol removed from the Omnicell Automated Medication Dispenser on the same date at the same time by the same anesthesiologist. Their surgical procedures started at different times, therefore, the medication for patient N5 was stored somewhere other than the Omnicell until the start of their procedure. | | | |

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| | Also, patient N4's anesthesia started at 11:29 AM, propofol was administered at approximately 11:30 AM, but it was not removed from the Omnicell until 11:47 AM. And, patient N3 had no propofol administered but it was removed from the Omnicell.<br><br>5. Medical Staff D1 was interviewed on 1/10/13 via speaker phone at approximately 10:22 AM, with Chief Clinical Officer present and listening and confirmed, [anesthesiologists] remove the Propofol prior to surgical procedures on that day for colonoscopies and we do put these vials into our pockets to be used during each patient's procedure to keep them secure. Facility policy and procedure is not being followed related to to drug storage and security, as well as documentation of rate and total dosage amount administered of anesthetic agents. | | | |

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| A1004 | 482.52(b)(2)<br>INPATIENT POST-ANESTHESIA EVALUATION<br>[The policies must ensure that the following are provided for each patient:]<br><br>An intraoperative anesthesia record.<br>Based on policy and procedure review, medical record review and staff interview, the facility failed to ensure intra-operative monitoring related to documentation of rate and total dosage amount of anesthetic agents according to policy and procedure for 3 of 5 (N2, N4, and N5) closed patient medical records reviewed.<br><br>Findings:<br><br>1. Policy No.: A-11 titled, "Anesthesia Care Protocol", revised/reapproved 5/2012, was reviewed on 1/10/13 at approximately 10:40 AM, and indicated on pgs. 6 & 7, under Practice Parameters and Procedures section, point I.7., "The anesthesiologist shall keep a complete record for each operation where he is in attendance on the approved anesthesia form. The Anesthesiologist is responsible for the recording of all events taking place during the induction, maintenance of, and emergence from anesthesia, including dosage and duration of all anesthetic agents, other drugs, and intravenous fluids." | A1004 | Effective 2/15/13 the Hospital implemented a new Drug Utilization Review policy to monitor and enforce compliance with Hospital policies for control, use and monitoring of drugs. The policy requires a quality monitor to monitor appropriate control, use, and monitoring of drugs. The medical records will be reviewed in accordance with the Drug Utlization Review Policy. The medical records regarding Propofol will be reviewed daily to determine compliance for until such time as the records properly document the required information ( including dosage and rate ). 30 records or more will be reviewed quarterly for compliacne and reported to the Anethesia Committee. . The Hospital is holding a mandatory meeting no later than March 12 with the anesthesiologists to review the Hospitals Policies regarding drug control, use and monitoring including the following. 1. Policy No PHAR470 titled: : Medication Storage."2. Policy No: A-11 titled: "Anesthesia Care and Protocol."3. New Drug Utilization Review Policy. The Hospital is forming an Anesthesia Committee of the medical staff on | 03/12/2013 |

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| | 2. Review of closed patient medical records on 1/10/13 at approximately 11:00 AM, indicated patient:<br><br>A. N2 had a surgical procedure performed on 10/18/12, under general anesthesia and at approximately 07:00 AM, 140 mg of propofol (10 mg/1 ml) was administered, and continued via drip beginning around 7:30 AM. This drip is documented as ..... across the form until approximately 09:00 AM. The Anesthesia Record lacked documentation of rate and total dosage amount of propofol administered during the surgical procedure.<br><br>B. N4 had a surgical procedure performed on 10/17/12, under monitored anesthesia care (with sedation) and at approximately 11:30 AM, 60 mg of propofol (10 mg/1 ml) was administered, and continued via drip beginning around 11:30 AM. This drip is documented as ..... across the form until approximately 11:52 AM. The Anesthesia Record lacked documentation of rate and total dosage amount of propofol administered during the surgical procedure.<br><br>C. N5 had a surgical procedure performed on 10/17/12, under monitored anesthesia care (with sedation) and at | | or before March 12, 2013, that will meet quarterly to review Drug Utilization Review and related matters. In regards to the specific issue of Propofol, rate and total dose documented, will bre reviewed daily by the Pharmacist to ascertain compliance is achieved. Pharmacist will determine if any deficiences are noted in the process. This information will be reported to the Anesthesia Committee and to Quality Counsil Committee. | |

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| | approximately 12:00 PM, 60 mg of propofol (10 mg/1 ml) was administered, and continued via drip beginning around 12:00 PM. This drip is documented as ..... across the form until approximately 12:24 PM. The Anesthesia Record lacked documentation of rate and total dosage amount of propofol administered during the surgical procedure.<br><br>3. Medical Staff D1 was interviewed on 1/10/13 via speaker phone at approximately 10:22 AM, with Chief Clinical Officer present and listening and confirmed, the initial amount of propofol administered is documented on the Anesthesia Record. Then if it is given via intravenous drip after that, it is written as ..... on the Anesthesia Record. The Anesthesia Record lacked documentation of rate and total dosage amount of propofol administered during the surgical procedure. | | | |

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| S0000 | This visit was for investigation of a State hospital complaint.<br><br>Complaint Number:<br>IN00118590<br>Substantiated: Deficiencies cited.<br><br>Date: 1/10/13<br><br>Facility Number: 006619<br><br>Surveyor: Jacqueline Brown, R.N.<br>Public Health Nurse Surveyor<br><br>QA: claugfhlin 02/11/13 | S0000 | | |

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| PINNACLE HOSPITAL | 9301 CONNECTICUT DR<br>CROWN POINT, IN 46307 |

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| S0406 | 410 IAC 15-1.4-2<br>QUALITY ASSESSMENT AND IMPROVEMENT<br>410 IAC 15-1.4-2(a)(1)<br><br>(a) The hospital shall have an effective, organized, hospital-wide, comprehensive quality assessment and improvement program in which all areas of the hospital participate. The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:<br><br>(1) All services, including services furnished by a contractor.<br>Based on policy and procedure review and staff interview, the facility failed to ensure that communication was implemented to notify the Quality/Risk Director of potential risk to patient safety allegations at the time the allegations were made in order to conduct timely follow up and investigation.<br><br>Findings:<br><br>1. Policy No.: QA titled, "Quality Mgmt Department Scope of Care", revised/reapproved 5/2012, was reviewed on 1/10/13 at approximately 10:40 AM and indicated on pg:<br>A. 1, under Organizational Plan and Structure section, points 3.1 and 3.2, "Quality/Risk Management Services functions under the direction of the | S0406 | The hospital hired a new Quality Risk Manager that has been fully oriented regarding her responsibilities under the applicable policies. The Manager has been fully integrated into operation of the Hospital and is engaged in her role. To ensure that all personnel understand the role of the Quality Risk Manager the Hospital will hold a general staff meeting for all personnel on or before March 13, 2013 regarding this issue.By way of further response, the Hospital notes following: Finding 2A: The allegation regarding the surgical tech witnessing an anesthesiologist putting Propofol in his pocket was reported to the COO of the Hospital ( who was temporarily serving as the Quality Risk Manager while the new Manager was trained ) who reported it to the Medical Director, | 03/13/2013 |

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| | Director of Quality/Risk Management. The Director, Quality/Risk Management, is responsible for the daily operations of the department and has the authority and responsibility for all aspects of planning, implementing, monitoring and evaluating the services and care delivered by the department."<br>B. 3, under Scope of Care/Activities includes, but not limited to section: Patient Safety, prevention of medical variances that can actually/potentially result in patient injury/harm through an environment that encourages: recognition and acknowledgement of risks to patient safety and medical/health care errors; initiation of actions to reduce these risks; internal reporting of what has been found and the actions taken."<br>C. 3 & 4, under Quality/Performance Improvement: an overall assessment of the efficiency and/or effectiveness of performance activities and/or care...Identifying problems/reasons for improvement to achieve external and internal customer satisfaction, improving organization performance or achieving strategic goals, analyzing root cause of identified problems/opportunities for improvement and implementing countermeasures to reduce or eliminate identified root causes and improve care...reporting and follow-up of unusual occurrences involving patients and | | the Chairman of the Medical Advisor Committee and Hospital counsel. The surgical tech was interviewed by the COO and Hospital counsel who denied making the accusation and refused to cooperate. In addition, the anesthesiologist denied to the CEO that he pocketed the propofol. During the survey, the anesthesiologist was questioned by the surveyor and conceded that he did in fact pocket the propofol. The Quality Risk Manager was notified of the admission and she has referred the matter to the Peer Review Committee which will consider what action should be taken at its meeting on March 13, 2013. The Quality Risk Manager, and Manager of Surgical Services will hold a meeting with the anesthesia department staff on or before March 12, 2013 to discuss the Policies relating to the proper handling of drugs and the need to report and cooperate with the Hospital Administration when it investigates these type of incidents In addition, the anesthesiologists will be inserviced on the proper documentation for intraoperative medication useage of rate and dose. In addition, the Pharmacist had begun reviewing charts on surgical patients for proper use and documentation of anesthesia ( Propofol ) on a daily basis to confirm that the applicable policies are being | |

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| | families, reduction, minimization and/or prevention of exposure to risk and/or litigations."<br><br>2. Personnel P6 was interviewed on 1/10/13 at approximately 10:06 AM and confirmed:<br>A. an allegation was made by a surgical tech that they witnessed an anesthesiologist putting Propofol in their pocket prior to a surgical procedure.<br>B. another allegation was made by a nurse that this same anesthesiologist left the facility while patients were still in the recovery room and threatened to have this nurse terminated if they reported it. This allegation was received via email from this nurse on 1/8/13.<br>C. the Quality/Risk Director was not made aware of either of these allegations and although they were recently hired and in training/orientation, he/she should have been made aware of these allegations as required by facility policy and procedure.<br><br>3. Personnel P3 was interviewed on 1/10/13 at approximately 9:32 AM and confirmed, he/she were not made aware of these two allegations. | | followed. The Pharmacist will cease daily review when she determines that the policies are being followed and she will do a Quarterly Review of 30 charts to determine they they properly reflect use and documentation of anesthesia ( Propofol ). The Hospital has formed an Anesthesia Committee which will review along with the Qualtiy Council the results of the audits done by the Pharmacist on a Quarterly basis. Finding 2B: The Post Anesthesia nurse reported to the surgical manager during a department meeting that a physician left the facility while patients were still in recovery room and threatened to have this nurse terminated if they reported it. This incident occured on December 29, 2012, and was reported to the surgical manager on January 8, 2013. The manager notified the COO by email and the COO instructed the manager to request an incident report from the nurse, which was provided on January 13, 2013. The Quality Manager received the report on January 11, 2013 at 12:30. The matter was discussed with the Medical Staff President who referred it to the Peer Review Committee to consider at its March 13, 2013 meeting. In addition, the Quality Risk Manager will hold a meeting with thre anesthesia department regarding the applicable policies relating to the presence of an | |

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| | | | anesthesiologist in the surgical area and the requirement that the Hospital staff report deviations from those policies as soon as possible | |

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| S1014 | 410 IAC 15-1.5-7<br>PHARMACEUTICAL SERVICES<br>410 IAC 15-1.5-7(c)<br><br>(c) In order to provide patient safety, the director of pharmacy shall develop and implement written policies and procedures for the appropriate selection, control, labeling, storage, use, monitoring, and quality assurance of all drugs and biologicals.<br>Based on policy and procedure review, medical record review, and staff interview, the facility failed to implement written policies and procedures for the appropriate control, use, and monitoring of drugs according to policy and procedure for 3 of 5 (N2, N4, and N5) closed patient medical records reviewed.<br><br>Findings:<br><br>1. Policy No.: PHAR470 titled, "Medication Storage", revised/reapproved 5/2012, was reviewed on 1/10/13 at approximately 10:40 AM, and indicated on pg. 1, under Policy section, "It is the policy of [facility] that medications will be stored in a safe manner and to meet all applicable laws and regulations with regards to drug storage and security."<br><br>2. Policy No.: A-11 titled, "Anesthesia Care Protocol", revised/reapproved 5/2012, was reviewed on 1/10/13 at | S1014 | Effective 2/15/13 the Hospital implemented a new Drug Utilization Review policy to monitor and enforce compliance with Hospital policies for control, use and monitoring of drugs. The policy requires a quality monitor to monitor appropriate control, use, and monitoring of drugs. The medical records will be reviewed in accordance with the Drug Utlization Review Policy. The medical records regarding Propofol will be reviewed daily to determine compliance for until such time as the records properly document the required information ( including dosage and rate ). 30 records or more will be reviewed quarterly for compliance and reported to the Anethesia Committee. The Hospital is holding a mandatory meeting no later than March 12 with anesthesiologists to review the Hospitals Policies regarding drug control, use and monitoring the following.1. Policy No: PHAR470 titled : "Medication Storage."2. Policy No: A-11 | 03/12/2013 |

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| | approximately 10:40 AM, and indicated on pgs. 6 & 7, under Practice Parameters and Procedures section, point I.7., "The anesthesiologist shall keep a complete record for each operation where he is in attendance on the approved anesthesia form. The Anesthesiologist is responsible for the recording of all events taking place during the induction, maintenance of, and emergence from anesthesia, including dosage and duration of all anesthetic agents, other drugs, and intravenous fluids."<br><br>3. Review of closed patient medical records on 1/10/13 at approximately 11:00 AM, indicated patient:<br><br>A. N2:<br>a. had a surgical procedure performed on 10/18/12, under general anesthesia starting at 06:54 AM.<br>b. per Omnicell Automated Medication Dispensing Report dated 10/18/12, the following was removed by D1 for N2 at:<br>i. 6:58 AM, one 100 ml vial of propofol 10 mg/1 ml.<br>ii. 8:12 AM, one 50 ml vial of propofol 10 mg/1 ml.<br>c. per Anesthesia Record dated 10/18/12:<br>i. D1 was listed as the anesthesiologist. | | titled:: " Anesthesia Care Protocol.3. New Drug Utilization Review Policy. The hospital is forming an Anesthesia Committee of the Medical staff on or before March 12, 2012, that will meet quarterly to review Drug Utilization Review and related matters. ain regards to the specific issue of Propofol, rate and total dose documented. will be reviewed daily by the Pharmacist to ascertain complaince is achieved. Pharmacist will determine if any deficiences are noted in the process. This information will be reported ti the Anesthesia Committee and to Quality Council Committee. | |

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| | ii. at approximately 07:00 AM, 140 mg of propofol was administered.<br>iii. lacked documentation of rate and total dosage amount of propofol administered during the surgical procedure<br><br>B. N3:<br>a. had a surgical procedure performed on 10/17/12, under monitored anesthesia care (with sedation) starting at 11:09 AM.<br>b. per Omnicell Automated Medication Dispensing Report dated 10/17/12, the following was removed by D1 for N3 at 11:12 AM, one 50 ml vial of propofol 10 mg/1 ml.<br>c. per Anesthesia Record dated 10/17/12:<br>i. D1 was listed as the anesthesiologist.<br>ii. no propofol was administered during the surgical procedure.<br><br>C. N4:<br>a. had a surgical procedure performed on 10/17/12, under monitored anesthesia care (with sedation) starting at 11:29 AM.<br>b. per Omnicell Automated Medication Dispensing Report dated 10/17/12, the following was removed by D1 for N4 at 11:47 AM, one 20 ml vial of propofol 10 mg/1 ml.<br>c. per Anesthesia Record dated 10/17/12: | | | |

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| | i. D1 was listed as the anesthesiologist.<br>ii. at approximately 11:30 AM, 60 mg of propofol was administered.<br>iii. lacked documentation of rate and total dosage amount of propofol administered during the surgical procedure<br><br>D. N5:<br>a. had a surgical procedure performed on 10/17/12, under monitored anesthesia care (with sedation) starting at 11:54 AM.<br>b. per Omnicell Automated Medication Dispensing Report dated 10/17/12, the following was removed by D1 for N5 at 11:47 AM, one 50 ml vial of propofol 10 mg/1 ml.<br>c. per Anesthesia Record dated 10/17/12:<br>i. D1 was listed as the anesthesiologist.<br>ii. at approximately 12:00 PM, 60 mg of propofol was administered.<br>iii. lacked documentation of rate and total dosage amount of propofol administered during the surgical procedure<br><br>4. Patients N4 and N5 had propofol removed from the Omnicell Automated Medication Dispenser on the same date at the same time by the same anesthesiologist. Their surgical | | | |

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| | procedures started at different times, therefore, the medication for patient N5 was stored somewhere other than the Omnicell until the start of their procedure. Also, patient N4's anesthesia started at 11:29 AM, propofol was administered at approximately 11:30 AM, but it was not removed from the Omnicell until 11:47 AM. And, patient N3 had no propofol administered but it was removed from the Omnicell.<br><br>5. Medical Staff D1 was interviewed on 1/10/13 via speaker phone at approximately 10:22 AM, with Chief Clinical Officer present and listening and confirmed, [anesthesiologists] remove the Propofol prior to surgical procedures on that day for colonoscopies and we do put these vials into our pockets to be used during each patient's procedure to keep them secure. Facility policy and procedure is not being followed related to to drug storage and security, as well as documentation of rate and total dosage amount administered of anesthetic agents. | | | |

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| S1428 | 410 IAC 15-1.6-1<br>ANESTHESIA SERVICES<br>410 IAC 15-1.6-1 (c)(3)<br><br>(c) Anesthesia services shall be consistent with needs and resources, as follows:<br><br>(3) There shall be intra-operative monitoring in accordance with current acceptable standards of practice.<br>Based on policy and procedure review, medical record review and staff interview, the facility failed to ensure intra-operative monitoring related to documentation of rate and total dosage amount of anesthetic agents according to policy and procedure for 3 of 5 (N2, N4, and N5) closed patient medical records reviewed.<br><br>Findings:<br><br>1. Policy No.: A-11 titled, "Anesthesia Care Protocol", revised/reapproved 5/2012, was reviewed on 1/10/13 at approximately 10:40 AM, and indicated on pgs. 6 & 7, under Practice Parameters and Procedures section, point I.7., "The anesthesiologist shall keep a complete record for each operation where he is in attendance on the approved anesthesia form. The Anesthesiologist is responsible for the recording of all events taking place during the induction, maintenance of, and emergence from anesthesia, including dosage and duration of all anesthetic | S1428 | Effective 2/15/13 the Hospital implemented a new Drug Utilization Review policy to monitor and enforce compliance with Hospital policies for control, use and monitoring of drugs. The policy requires a quality monitor to monitor appropriate control, use, and monitoring of drugs. The medical records will be reviewed in accordance with the Drug Utlization Review Policy. The medical records regarding Propofol will be reviewed daily to determine compliance for until such time as the records properly document the required information ( including dosage and rate ). 30 records or more will be reviewed quarterly for compliance and reported to the Anethesia Committee. The Hospital is holding a mandatory meeting no later then March 12 with anesthesiologists to review the Hospital Policies regarding drug control, use and monitoring including the following.1. Policy No: PHAR470 titled : " Medication Storage."2. Policy No: A-11 titled: "Anesthesia Care Protocol."3. | 03/12/2013 |

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| | agents, other drugs, and intravenous fluids."<br><br>2. Review of closed patient medical records on 1/10/13 at approximately 11:00 AM, indicated patient:<br><br>A. N2 had a surgical procedure performed on 10/18/12, under general anesthesia and at approximately 07:00 AM, 140 mg of propofol (10 mg/1 ml) was administered, and continued via drip beginning around 7:30 AM. This drip is documented as ..... across the form until approximately 09:00 AM. The Anesthesia Record lacked documentation of rate and total dosage amount of propofol administered during the surgical procedure.<br><br>B. N4 had a surgical procedure performed on 10/17/12, under monitored anesthesia care (with sedation) and at approximately 11:30 AM, 60 mg of propofol (10 mg/1 ml) was administered, and continued via drip beginning around 11:30 AM. This drip is documented as ..... across the form until approximately 11:52 AM. The Anesthesia Record lacked documentation of rate and total dosage amount of propofol administered during the surgical procedure. | | New Drug Utilization Review Policy. The Hospital is forming an Anesthesia Committee of the medical staff on or before March 12, 2013, that will meet quarterly to review Drug Utilization Review and related matters. In regards to the specific issue of Propofol, rate and total dose documented, will be reviewed daily by the Pharmacist to ascertain compliance is achieved. Pharmacist will determine if any deficiences are noted in the process. This information will be reported to Anesthesia Committee and to Quality Council Committee. | |

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| | C. N5 had a surgical procedure performed on 10/17/12, under monitored anesthesia care (with sedation) and at approximately 12:00 PM, 60 mg of propofol (10 mg/1 ml) was administered, and continued via drip beginning around 12:00 PM. This drip is documented as ..... across the form until approximately 12:24 PM. The Anesthesia Record lacked documentation of rate and total dosage amount of propofol administered during the surgical procedure.<br><br>3. Medical Staff D1 was interviewed on 1/10/13 via speaker phone at approximately 10:22 AM, with Chief Clinical Officer present and listening and confirmed, the initial amount of propofol administered is documented on the Anesthesia Record. Then if it is given via intravenous drip after that, it is written as ..... on the Anesthesia Record. The Anesthesia Record lacked documentation of rate and total dosage amount of propofol administered during the surgical procedure. | | | |